IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

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PATENT & TRADEMARK OFFICE

Appellant: Louis Woo
Serial No: 10/685,809
Filed: October 16, 2003
For: DILATORS

Art Unit: 3767
Examiner: Anderson, Michael J.
Attorney Docket: 0119/0017

APPEAL BRIEF

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REAL PARTY IN INTEREST

The real party in interest of the subject application is Smiths Group plc to whom the inventor assigned his invention per an Assignment recorded October 16, 2003 on Reel 014614, Frame 0681 at the Assignment Branch of the U.S. Patent and Trademark Office.

RELATED APPEALS AND INTERFERENCES

As far as is known, there are no appeals or interferences that are related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-12 are pending in the application, and are being appealed herein.

Being appealed claims 1-12, reproduced in the Claims Appendix, have been rejected per the Office Action dated August 19, 2008.

STATUS OF AMENDMENTS

There was no amendment filed in response to the Office Action of August 19, 2008.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent claim 1 is directed to a tracheostomy dilator (Figs. 1, 4) that includes a patient end region (3) that is curved, tapered and adapted for insertion through a tracheostomy to expand the tracheostomy as it is being inserted, and a handle region (5) at an end of the dilator opposite to the patient end region. The handle region is curved in an opposite sense from the patient end region. [Page 4, lines 6-10]

Dependent claim 2 defines the dilator to have a passage (10) that extends along the dilator for receiving a guide member. [Fig. 2; page 4, lines 11-12]

Claim 3 depends from claim 2 which in turn depends from claim 1, and recites a tip (2) of the patient end region that provides a substantially stepless transition with an outer surface of the guide member. [Figs. 1, 3; page 5, lines 7-9]

Claim 4 defines the handle region (5) to have a substantially constant diameter along its length. [Figs. 1, 3; page 4, line 4]

Claim 5 defines the handle region (5) to have surface formations (9) to enhance the grip. [Figs. 1-, 3; page 4, line 5]

Claim 6 defines the dilator to be molded from a plastics material. [Page 3, lines 7-8]

Claim 7 defines the plastics material to have a Shore hardness of substantially 90A. [Page 3, lines 7-8]

Claim 8 defines the radius of the curvature of the handle region (5) to be substantially the same as that of the patient end region (3). [Fig. 1; page 4, lines 8-9]

Claim 9 defines the radius of the curvature of the patient end (3) to be about 90mm. [Page 4, line 8]

Claim 10 defines the dilator of claim 1 to include a coating of hydrophillic material along its patient end region. [Page 4, lines 15-16]

Independent claim 11 recites a tracheostomy dilator that has one end providing a handle region (5) and an opposite end providing a flexible, tapered patient end region (3) for insertion to the trachea. The dilator is defined to be smoothly curved along substantially its entire length with an S shape. [Fig. 1, page 3, lines 12-15 and page 4, lines 6-10]

Independent claim 12 recites a tracheostomy dilator that includes a patient end rejection (3) that is tapered along its length [page 3, lines 14-15], an intermediate region (4) that tapers along its length substantially less than the patient end region [page 4, lines 1-3], and a handle end region (5) that has a substantially constant diameter along its length [page 4, lines 4-5]. The dilator has a passage (10) that extends within it and opens at a tip (2) of the patient end rejection to accommodate a guide member along which the dilator is inserted into the trachea [page 2, line 12; page 14, lines 11-12]. The wall thickness of the patient end region is reduced towards the patient end tip so as to provide a smooth transition with an outer surface of the guide member [page 4, lines 12-14; page 5, lines 6-9], and the dilator is curved along substantially its entire length to an S shape so that the dilator can be held in the hand and inserted into the trachea ergonomically [Fig. 4, page 4, lines 6-10; page 5, line 12 to page 6, line 2].

Simply put, the at issue tracheostomy tube dilator is an S shaped dilator that smoothly curves along substantially its entire length, with its handle region curving in an opposite sense as its patient region.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-12 stand rejected under 35 U.S.C. §102 (b) as being unpatentable over Ciaglia et al. publication (US 2002/0066453).

ARGUMENT

35 U.S.C. 102(b) rejection of Claims 1-12 under Ciaglia et al. (US 2002/0066453)

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. ... The identical invention must be shown in as complete detail as is contained in the ... claim. ...The elements must be arranged as required in the claim ..." MPEP § 2131.

Independent claim 1 specifically recites that the handle region of the claimed tracheostomy dilator is curved in an opposite sense from the patient end region.

Independent claim 11 requires that the dilator be smoothly curved along substantially its entire length with an S shape.

Independent claim 12 requires that the dilator be curved substantially along its entire length to a S shape so that the dilator can be held in the hand and inserted into the trachea ergonomically.

Ciaglia discloses a dilator that is in the shape of a rhinoceros horn, in that there is curvature only from the distal end 20 to the demarcation line 22 (and possibly to insertion line 26) at the tapered distal portion 16 of the dilator (see Fig. 2). Indeed, Ciaglia discloses throughout that it is only the tapered distal portion 16 that is curved. See for example the first and last sentences in paragraph 0016 and the first sentence in paragraph 0018.

There is nothing in Ciaglia that discloses or suggests that the handle portion of his tracheostomy dilator is curved, let alone curved in the opposite sense from the patient end region as required in claim 1, or that the dilator be in the shape of an S, as required in claims 11 and 12.

The examiner has relied on paragraphs 0006 and 0019 of Ciaglia to support his assertion that Ciaglia teaches the claimed invention.[1]

Paragraphs 0006 and 0019 of Ciaglia are reproduced hereinbelow:

> "The single dilator includes a soft, pliant tapered tip identical in shape and size and in tip inner diameter to those of the prior art dilators, and additionally includes a curved distal portion extending from the tapered tip toward the proximal end, and the **generally linear shaft**. The curved distal portion is tapered to extend from a diameter of 12 french (for example) adjacent the tapered tip, to a diameter of 38 french adjacent **the linear shaft**. Preferably both the curvature and the taper of the curved tapered distal portion from the distal tip to the shaft is gradual with no discontinuities. Also preferably, the curved tapered distal portion has a gradual transition in flexibility from very flexible at the short distal tip portion to generally rigid at **the generally linear shaft portion**, such as by gradually changing its wall thickness." [0006]
>
> "The curvature of curved tapered distal portion 16 may be a series of curves of different radii, or a complex curve, from distal end 20 at least to demarcation 22. The portion of dilator 10 between demarcation 22 and insertion limit 26 will extend, during use of the dilator, between the outer skin of the patient and the inside or anterior surface of the trachea of the patient. Also, the optimum curvature may be within a range such that the outer surfaces are within a zone of tolerance. While not susceptible of a precise mathematic definition, it is preferred that the curvature be complementary to the curvature of conventional curved tracheostomy tubes." [0019] [Underlines added with terms bolded.]

If anything, paragraph 0006 of Ciaglia confirms that the curved distal portion (16) extends from the distal end (20) to the **linear shaft** (12). Putting it simply, shaft (12) of the Ciaglia device is linear. This is also clearly shown in Figs. 2 and 3 of Ciaglia. As for paragraph 0019, Ciaglia discloses there that the curved tapered distal portion (16) may be formed from a series of curves of different radii, and that the curvature of the distal portion may be complementary to the curvature of conventional curved tracheostomy tubes. That the Ciaglia distal portion may be formed from curves of different radii has nothing to do with the linear shaft of the Ciaglia dilator. If anything, it confirms that it is only the distal portion of Ciaglia dilator that is curved. That the curvature of the distal portion of the Ciaglia dilator may be complementary to curved tracheostomy tubes also has no bearing on the linear shaft of the Ciaglia dilator. This is so that after the desired opening is made by the Ciaglia dilator at the trachea of the patient, a complementary curved tracheostomy tube may be inserted through the widened tracheal opening into the patient (see paragraph 0024).

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[1] In the 1st full paragraph on page 3 of the Office Action of August 18, 2008, the Examiner states: "Provisions are provided (pp[0006, 0019]) for the handle to be curved in an opposite direction of the distal portion."

As noted above, a prior art reference for a section 102 rejection must show all the elements of a claim, and the elements must be arranged as required in the claim. Ciaglia does neither. Rather, it teaches the opposite, in that it specifically discloses that his device has a linear shaft. That being the case, it is respectfully submitted that Ciaglia does not anticipate the claimed invention but instead actually teaches away from the claimed invention as particularly set forth in independent claims 1, 11 and 12.

In view of the above, appellant respectfully submits that the rejection of independent claims 1, 11 and 12, and claims 4-10 dependent from claim 1, is without merit and not sustainable.

Conclusion

For the reasons pointed out above, appellant respectfully submits that the pending claims on appeal are patentably distinguishable over the cited reference and that the examiner's rejection accordingly is without merit and not sustainable. The Board is therefore respectfully requested to reverse the examiner's rejection.

Respectfully submitted,

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CLAIMS APPENDIX

1. A tracheostomy dilator comprising: a patient end region, said patient end region being curved, tapered and adapted for insertion through a tracheostomy to expand the tracheostomy as it is inserted; and a handle region at an end of the dilator opposite said patient end region, wherein said handle region is curved in an opposite sense from said patient end region.

2. A dilator according to Claim 1, wherein said dilator has a passage extending along it for receiving a guide member.

3. A dilator according to Claim 2, wherein a tip of said patient end region provides a substantially stepless transition with an outer surface of said guide member.

4. A dilator according to Claim 1, wherein said handle region has a substantially constant diameter along its length.

5. A dilator according to Claim 1, wherein said handle region has surface formations adapted to enhance grip.

6. A dilator according to Claim 1, wherein said dilator is moulded of a plastics material.

7. A dilator according to Claim 6, wherein said plastics material has a Shore hardness of substantially 90A.

8. A dilator according to Claim 1, wherein the radius of a curvature of said handle region is substantially the same as that of said patient end region.

9. A dilator according to Claim 1, wherein the radius of curvature of said patient end is about 90mm.

10. A dilator according to Claim 1 including a coating of a hydrophilic material along its patient end region.

11. A tracheostomy dilator comprising one end providing a handle region and an opposite end providing a flexible, tapered patient end region for insertion to the trachea, wherein said dilator is smoothly curved along substantially its entire length with an S shape.

12. A tracheostomy dilator comprising: a patient end region, said patient end region tapering along its length; an intermediate region, said intermediate region tapering along its length substantially less than said patient end region; and a handle end region, said handle end region having a substantially constant diameter along its length, wherein said dilator has a passage extending within it and opening at a tip of said patient end region to accommodate a guide member along which said dilator is inserted to the trachea, wherein the wall thickness of said patient end region reduces towards a patient end tip such as to form a smooth transition with an outer surface of said guide member, and wherein said dilator is curved along substantially its entire length to an S shape so that the dilator can be held in the hand and inserted into the trachea ergonomically.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.